IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

William W. Cimino

Examiner:

Laura A. Bouchelle

Serial No.:

10/600,118

Group Art Unit:

3763

Filed:

June 20, 2003

Docket. No.:

40206.19US01

Title:

"Precision Fluid Delivery System and Method for Surgical Procedures"

<u>DECLARATION UNDER 37 C.F.R. § 1.132</u> <u>BY DANIEL S. GOLDBERGER</u>

Mail Stop Amendment Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

- I, Daniel S. Goldberger, declare that:
- 1. I am the Chief Executive Officer of Sound Surgical Technologies LLC ("Sound Surgical") assignee of U.S. Patent Application Serial No. 10/600,118 (the "present application") identified above and the invention described therein. I have been CEO of Sound Surgical since April 2007.
- 2. I received a Bachelor of Science degree in mechanical engineering from the Massachusetts Institute of Technology, and a Master of Science degree in mechanical engineering from Stanford University.
- 3. I have been involved in the medical device field since 1979. Among other positions, in 1994 I co-founded Optiscan Biomedical Corporation. From 2001 to 2004, I was president of the Medical Group of OSI Systems (a NASDAQ traded company), including Spacelabs Medical, Dolphin Medical, and Osteometer. Immediately prior to joining Sound

Surgical, I was Chief Executive Officer of Glucon, Inc., a developer of glucose monitoring devices based on photoaccoustic principles.

- 4. I am an inventor on more than 50 U.S. patents in the medical device field. I have basic understanding of the principles regarding the validity and infringement of U.S. patents. I have attached a copy of my Curriculum Vitae to this Declaration as Exhibit A.¹
- 5. I am generally familiar with the industry relating to cosmetic/aesthetic surgery including lipoplasty, Ultrasonic Assisted Lipoplasty (UAL), body contouring, and related procedures including breast enhancement and reduction. This knowledge has been obtained from my education and experience outlined above and specifically from my involvement in all facets of Sound Surgical's business including interaction with customers and potential customers, attendance at trade shows, conventions, and seminars. As a result of these activities, I have a working knowledge of the products available in these markets including those available from competitors of Sound Surgical.
- 6. I am aware that the present application is currently rejected by the United States Patent Office, and that this Declaration is being submitted in support of arguments against the obviousness of the invention claimed in the present application.
- 7. The invention claimed in the present application is embodied in a precision fluid management system (PFMS) sold as part of Sound Surgical's VASER system since 2004.
- 8. I have reviewed the Declaration of Dr. Mark Jewell, M.D., submitted in connection in the present patent application in support of arguments against the obviousness of the invention claimed in the present application. I find the statements made in Dr. Jewell's Declaration consistent with my knowledge and experience regarding equipment and procedures for precisely monitoring rapid fluid flow for aesthetic medical procedures. Simply stated, to the best of my knowledge, the device described and claimed in the present patent application is the

¹ Exhibit A is not being filed herewith. A supplemental filing will be made with Exhibit A including Mr. Goldberger's Curriculum Vitae.

first device available to the market that can precisely monitor rapid fluid flow for aesthetic medical procedures such as UAL procedures.

- 9. The only other commercial devices that I am aware of that purport to provide the capability of precisely monitoring rapid fluid flow for aesthetic medical procedures (i.e., the EZ PumpTM by Mentor and Tumescent Measuring Device by M.D. Resources referred to in paragraphs 10 and 11, respectively below) are "knock—offs" (i.e., copies) of the PFMS sold as part of Sound Surgical's VASER system, which embodies the principles of the pending patent application. The Mentor device and the M.D. Resources device were both introduced to the market after Sound Surgical introduced its popular PFMS.
- 10. I have attached to this Declaration as Exhibit B product literature of the EZ PumpTM product. I have reviewed the literature and the EZ PumpTM product and believe that it includes all of the features of at least one apparatus claim in the present application and when used in practice for its intended purpose would utilize all of the features of at least one method claim in the present patent application.
- 11. I have attached to this Declaration as Exhibit C product literature of the Tumescent Measuring Device product. I have reviewed the literature and the Tumescent Measuring Device product and believe that when used with the requisite pump it includes all of the features of at least one apparatus claim in the present application and when used in practice for its intended purpose would utilize all of the features of at least one method claim in the present patent application.
- 12. Other than Sound Surgical's PFMS, and the copies mentioned above, I am unaware of any other system or method for rapidly and precisely delivering fluid in aesthetic medical procedures.
- 13. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are

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punishable by fine or imprisonment or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the instant application or any patent issued thereupon.

February 22, 2011		
	Daniel S. Goldberger ²	

² This declaration is being submitted without Mr. Golberger's signature. However, a copy of this declaration with Mr. Goldberger's signature will be subsequently filed to supplement this filing.

PATENT

CONF. NO. 9143

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EXHIBIT A

CURRICULUM VITAE OF DANIEL S. GOLDBERGER

[The Curriculum Vitae will be provided in a supplemental filing.]

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EXHIBIT B

LITERATURE:

PRODUCT LITERATURE FOR THE EZ PUMP TM PRODUCT

The largest selection of Infiltration Systems known worldwide for convenience, reliability, and accuracy.

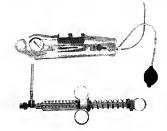
- EZ PUMP™
- PSI-TEC™ Infiltrator
- Big Bag 3000
- BP Cuff[™]

Infiltration Systems - Infiltrators



Catalog #	Oescription	
EZ-PUMP	Peristaltic Infiltration/Irrigation Pump	
BB3000	Big Bag 3000 (500 cc - 3000 cc capacity)	
PT-PINF-III	PSI-TEC III™ Infiltrator	
	A compact system featuring easy set up and adjustable flow control.	
	 Small footprint and ultra compact design 	
	 Powerful micro pump delivering open flow rate of 600 ml/minute. 	
BP CUFF	BP Cuff™ 1000 ml Unit Complete	

Infiltration Systems - Accessories



Catalog #	Oescription	Quantity
BP CUFF-G	Pressure Gauge 0-760 mm Hg	EA
BP CUFF-B	Squeeze Bulb, Male Luer Lock & 4-way Stopcock	EA
BP CUFF-E	Extension for 3-Liter Bag	EA

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EXHIBIT C

LITERATURE:

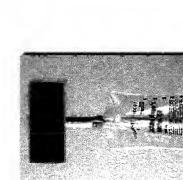
PRODUCT LITERATURE FOR THE TUMESCENT MEASURING DEVICE PRODUCT



* Store Front * Account * Search * Product List * Basket Contents

Order Today 800,633,8423 · Checkout

Tumescent Measuring Device



Quantity in Basket: none Code: TMD Price: \$650.00

Shipping Weight: 10.00 pounds

Please call for quote:

Quantity: 1

Add To Basket

Please call for quote.

With an innovative design, the TMD continues the M. D. Resource line of devices for tumescent procedures.

Its convenient pole top mount delivers effortless measurement of total tumescent delivery. Weight lost from the hanging tumescent fluid bag is digitally displayed with +/- 1 ml accuracy.

The very low current circuitry enables the TMD to be □piggy backed□ to our KPump or it can be used as a □stand-alone□ device.

SPECIFICATIONS

Start
Switch DDDDDDDD...

Once for □on□, once for □off□. Starts or restarts at 0 (zero).

Power	Supplied AC adapter provides 24 VDC @ 1 A. Operates with DC power supply of 8 to 40 volts @ 100 mA.
Hook	Stainless steel hook accommodates up to 3 saline bags.
Load Limit	Up to 4,000 ml (4 kg) maximum advised load.
Mounting	Mounts on adjustable height pole with 7/8(.875)□ O.D.